UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOLOFT (SERTRALINE HYDROCHLORIDE) PRODUCTS LIABILITY LITIGATION	:	**MDL NO. 2342** **12-MD-2342** **HON. CYNTHIA M. RUFE**
This Document relates to: ALL ACTIONS	:	

PSC'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR LEAVE TO IDENTIFY AND PRESENT A NEW GENERAL CAUSATION EXPERT AND SETTING FORTH THE PSC'S POSITION ON VOLUNTARY DISMISSAL OF CERTAIN CASES WIHOUT PREJUDICE

I. PROCEDURAL HISTORY AND STATEMENT OF THE FACTS

Prior to April 17, 2012 there were 92 civil actions pending in various federal district courts in which minor plaintiffs claimed that they suffered from a variety of birth defects as a consequence of *in utero* exposure to Zoloft, a medication that continues to be marketed by Defendant, Pfizer, for the treatment of depression and other ailments. *In re Zoloft (Sertraline Hydrochloride) Products Liab. Litig.*, 856 F.Supp. 2d 1347, 1347 (J.P.M.D.L. 2012). As is typical in "mass tort" litigation, civil actions making substantially the same allegations were also filed in various state courts throughout the nation.

On April 17, 2012, the Judicial Panel for Multidistrict Litigation directed the transfer of the federal Zoloft cases to this Court for coordinated or consolidated pretrial proceedings as MDL No. 2342, finding that "centralized proceedings" would likely

"help[] to efficiently resolve" the overall litigation.[1] *Id*. at 1348-49. Upon transfer, this Court entered a series of pretrial orders designed to move the litigation towards resolution. First, the Court appointed a Plaintiffs' Steering Committee ("PSC") to assist in the management of the MDL proceedings. *See* Pretrial Order No. ("PTO") 6 (Doc. No. 202). Second, it provided a schedule for the PSC to identify expert witnesses on the subject of "general causation"[2] and to disclose the anticipated substance of their testimony. *See* PTOs 23 (Doc. No. 437), 39 (Doc. No. 612). Third, it promulgated a schedule for Pfizer to file *Daubert* motions directed to the legal sufficiency of the proposed testimony by the PSC's general causation experts and for the Court to conduct an evidentiary hearing on such motions. *Id*. Finally, it laid down a timetable for selecting twenty-five cases to be included in an Initial Discovery Pool and for selecting from those Initial Discovery Pool cases six cases for inclusion in an Initial Trial Pool, for disclosure of case-specific causation testimony in the Initial Trial Pool cases and for the completion of discovery and pretrial preparations in those cases. *See* PTOs 44 (Doc. No. 640), 57 (Doc. No. 841), 63 (Doc. No. 949). This timetable was designed to bring the first of the Initial Trial Pool cases to trial in January 2015. *Id.*

Pursuant to the Court's case management plan, the PSC timely identified and provided reports by four general causation experts: (a) Anick Bérard, a perinatal

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[1] After entry of its initial transfer order, the JPML continued to transfer newly filed federal cases to this District. At present there are nearly 600 minor plaintiffs with claims alleging Zoloft-induced birth defects that are before this court as part of the consolidated MDL proceedings in this District.

[2] "Courts in toxic tort cases often separate the causation inquiry into general causation -- whether the substance is capable of causing the observed harm in general -- and specific causation -- whether the substance actually caused the harm a particular individual suffered." *Perry v. Novartis Pharmaceuticals Corp*., 564 F.Supp.2d 452, 463 (E.D. Pa. 2008).

pharmacoepidemiologist with a Ph.D. in Epidemiology and Biostatistics from McGill University; (b) Thomas Sadler, an embryologist with a Ph.D. in anatomy and embryology; (c) Robert M. Cabrera, a teratologist with a Ph.D. in Medical Sciences, whose research focuses on identifying agents that may cause or prevent birth defects; and (d) Michael Levin, a molecular developmental biologist with a doctorate in genetics whose research interests included mechanisms that govern the patterning of embryos. *See* Mem. Op. dated 6/27/2014 (Doc. No. 979) at 1; Mem. Op. dated 8/12/2014 (Doc. No. 1033) at 3, 6, 7. After discovery of these experts was completed, Pfizer timely filed *Daubert* motions in which it sought to exclude their testimony on the grounds that their opinions were not the product of a scientifically reliable methodology.

After conducting an evidentiary hearing, the Court issued opinions dated June 27, 2014 and August 12, 2014 in which it adjudicated the *Daubert* motions. It ruled that Drs. Sadler, Cabrera, and Levin could offer their opinions on the biological plausibility of Zoloft causing a variety of birth defects. However, the Court held, none of the PSC's generic causation experts could offer the opinion that *in utero* exposure to Zoloft could cause any teratogenic effects in humans. In reaching this conclusion, the Court found that "before concluding that there is a 'true' association between a medication and an adverse outcome, the teratology community requires repeated, consistent, statistically significant human epidemiological findings, and studies which address suspected confounders and biases." *See* Mem. Op. dated 6/27/2014 (Doc. No. 979) at 6. According to the Court, the PSC's experts – principally Dr. Bérard[3] – failed to follow this

[3] In this regard the Court noted:

methodology and instead utilized the "novel" statistical methodology advocated in Kenneth Rothman's textbook on epidemiology,[4] impermissibly:

> deriv[ing] her conclusions about causation, in large part, by charting published findings from various studies (sometimes inaccurately) on a 'forest plot' (a graphical depiction of the odds ratios and confidence intervals from multiple studies), and drawing conclusions from trends in odds ratios depicted on the forest plot without regard to whether the underlying published findings were statistically significant, and without further statistical analysis. *Id*. at 8.

In addition, the Court found, Dr. Bérard improperly employed a "methodology [that] is not reliable or scientifically sound" by engaging in "cherry-picking" of studies and of

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> that Drs. Cabrera, Sadler, and Levin were retained for their expertise on biological mechanisms, and although they each reviewed the epidemiological literature, it was Dr. Bérard who was retained for her expertise in that field. Had the Court found Dr. Bérard's methodology was sound, they would have been justified in relying upon her report as evidence in support of their own human causation opinions.

Mem. Op. dated 8/12/2014 (Doc. No. 1033) at 16 n. 45.

[4] Dr. Rothman's approach to epidemiological evaluation of causation eschews reliance on arbitrary statistical significance limits in favor of a more holistic evaluation of the available data. Far from being "novel" this approach is, we believe, the state of the art in epidemiology. Indeed, as long ago as 1990, our Court of Appeals explicitly recognized that the "Rothman methodology" could be an appropriate approach to evaluating causation. *See DeLuca by Deluca v. Merrell Dow Pharmaceuticals, Inc*., 911 F.2d 941, 946-949, 953, 954-56 (3rd Cir. 1990). This viewpoint has seemingly been adopted by the Supreme Court in its recent *Matrix Initiatives* decision and by District Courts in a variety of *Daubert* rulings relating to pharmacological causation. *See Matrix Initiatives, Inc. v. Siracusano*, 131 S.Ct. 1309, 1319-20 (2011) ("A lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug and adverse events. [M]edical experts rely on other evidence to establish an inference of causation. We note that courts frequently permit expert testimony on causation based on evidence other than statistical significance. '[M]edical professionals and researchers do not limit the data they consider to the results of randomized clinical trials or to statistically significant evidence.'")(citations omitted); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig*., 289 F.Supp.2d 1230, 1241 (W.D.Wash. 2003) (on a *Daubert* motion involving general causation evidence in an MDL matter, lack of statistical significance under some circumstances "does not detract from the reliability of the study."); *In re Viagra Products Liab. Litig*., 572 F.Supp.2d 1071, 1081 (D. Minn. 2008) (same); *In re Neurontin Marketing, Sales Practices and Products Liab. Litig*., 612 F. Supp. 2d 116, 141 (D. Mass. 2009) (same).

findings within studies, "selectively discuss[ing] studies most supportive of her conclusions…and fail[ing] to account adequately for contrary evidence…." *Id*. at 16.

After entering the orders excluding the causation opinions proffered by Drs. Bérard, Sadler, Cabrera, and Levin, the Court entered orders staying all proceedings in MDL 2342 to allow due deliberation regarding the future procedural course of the litigation. *See* Pretrial Order Nos. 66 (Doc. No. 982), 69 (Doc. No. 1036), 71 (Doc. No. 1040), 72 (Doc. No. 1051).

Anxious to press its *Daubert* win to complete victory, Pfizer quickly proclaimed that the Court's *Daubert* opinions make it impossible for any MDL plaintiff to prove the critical tort element of causation and thus presently require the entry of summary judgment against all plaintiffs herein. *See* Defendants' Motion for Leave to File a Motion for Summary Judgment Under the Standard Approach filed on 8/21/2014) (Doc. No. 1041). Even considered apart from the circumstance that plaintiffs have not yet had the opportunity to move for reconsideration of the Court's *Daubert* rulings by reason of the post-ruling stays[5] and apart from the fact that none of the MDL cases are presently ripe for consideration of summary judgment,[6] acceding to Pfizer's literal rush to

[5] Within a reasonable period of time after the Court lifts the post-*Daubert* ruling stay the PSC intends to file a motion for partial reconsideration of the Court's previous *Daubert* rulings. It is likely that the motion for reconsideration will be supported by a declaration from one or more prominent epidemiologists concerning appropriate epidemiological and/or statistical methodologies for determination of general causation issues.

[6] An MDL transfer order is not equivalent to an order certifying a class under Fed.R.Civ.P. 23; civil actions do not relinquish their individual nature because they are subject to an MDL transfer. *E.g., Amchem Prods., Inc v. Windsor*, 521 U.S. 591, 617 (1997) *citing and quoting Georgine v. Amchem Prods., Inc*., 83 F.3d 610, 633 (3rd Cir. 1996) ("Each plaintiff in an action involving claims for personal injury and death has a significant interest in individually controlling the prosecution of his case"). Therefore, product liability plaintiffs are not bound by the results of an MDL common issues

judgment would effectively remit the viability of the Zoloft MDL to the Court of Appeals and would shift the center of gravity in the litigation of this mass tort from this Court to the various state judicial systems. While the PSC believes that it has good arguments to advance at the appellate level,[7] it also has great respect for the exercise of the Court's considerable discretion in discharging its role as gatekeeper for the presentation of scientific opinion evidence. Therefore, the PSC believes that the litigation can and should proceed in a manner that is not only consistent with the reasoning underlying this Court's *Daubert* rulings but that also does not involve the entry of summary judgment against any plaintiff.

Our belief in this regard stems from three critical aspects of the Court's *Daubert* rulings:

First, the Court did not rule that the currently available scientific information could never reliably support an opinion that *in utero* exposure to Zoloft can cause one or more birth defects. Rather, it ruled Drs. Bérard, Sadler, Cabrera, and Levin could not testify to their generic causation opinions because the specific methodology that was used to reach those opinions was not a scientifically reliable one.

Second, the Court recognized that there are multiple epidemiological studies that demonstrate a statistically significant increased risk of congenital heart defects in

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adjudication in which they were not parties. *DeLuca*, 911 F.2d at 952. Given this, each of the individual plaintiffs in MDL 2342 is entitled to present case-specific expert testimony that supports the contention that Zoloft caused his or her specific birth defect. At this point in the litigation, none of the individual MDL plaintiffs have had that opportunity, rendering premature consideration of summary judgment based on the absence of causation proof.

[7] *See* fn. 4, *supra*.

children exposed to Zoloft *in utero* that might properly support a causation opinion under *Daubert*. *See* Mem. Op. dated 6/27/2014 (Doc. No. 979) at 13-14, 20.

Third, with the continued marketing of Zoloft and intense scientific interest in its potential teratogenic effects, the Court recognized the prospect of emerging scientific evidence that might well provide reliable support for the conclusion that Zoloft causes a variety of specific birth defects, stating that "sound epidemiological evidence of a [teratogenic] effect may develop in the future…" *See* Mem. Op. dated 6/27/14 (Doc. No. 979) at 16. Because the injured plaintiffs in this litigation are minors and because the limitations period in most states does not even begin to run on a minor's claim until he or she reaches the age of majority,[8] these plaintiffs are not otherwise foreclosed from taking advantage of advances in scientific knowledge that occur over the next 15 to 20 years to the extent that these advances allow them to prove the essential causation element of their tort claims against Pfizer.

Given these features of the Court's *Daubert* opinions, the PSC is requesting relief in two different forms. First, pursuant to Fed.R.Civ.P. 16(b)(4), the PSC hereby requests that the Court amend the relevant case management orders to allow it to present generic expert testimony by Nicholas Jewell, Ph.D. Dr. Jewell is a professor in the Division of Biostatistics, School of Public Health and in the Department of Statistics, both at the

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[8] By way of example, Pennsylvania law provides that:

> If an individual entitled to bring a civil action is an unemancipated minor at the time the cause of action accrues, the period of minority shall not be deemed a portion of the time period within which the action must be commenced. Such person shall have the same time for commencing an action after attaining majority as is allowed to others by the provisions of this subchapter.

42 Pa.C.S.A. §5533(b)(1)(i).

University of California, Berkeley. Based largely on the existing studies that were in evidence at the past *Daubert* hearing,[9] Dr. Jewell will opine that *in utero* exposure to Zoloft can cause congenital heart defects. A proffer of Dr. Jewell's proposed testimony is reflected in the report that is appended as Exhibit "A" to the instant motion.[10] Second, the PSC contemplates that at an appropriate time in the future it will request that the Court enter an order pursuant to Fed.R.Civ.P. 41(a)(2) granting any MDL plaintiff who is without legally cognizable proof of causation leave to voluntarily dismiss his or her claim without prejudice.[11]

II. ARGUMENT

A. The Court Should Amend the Applicable Pretrial Orders to Allow the PSC an Opportunity to Identify and Present A New Expert to Testify that In Utero Exposure to Zoloft Can Cause Cardiac Birth Defects

The question of whether a court should permit a party to offer testimony by an expert witness who was first identified after the close of the period for expert discovery is one committed to the discretion of the District Court.[12] *E.g., ZF Meritor, LLC v. Eaton*

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[9] For the sake of completeness, Dr. Jewell has considered the results of several scientific studies that were not available at the time Dr. Bérard authored her report in this matter.

[10] The report attached as Exhibit "A" to this motion does not include appendices and the like. In the event that the Court grants the present motion, or should the Court request it, the PSC will furnish to the Court and Pfizer a final report by Dr. Jewell with all of the appendices included.

[11] Although the PSC is not presently moving for relief under Rule 41(a)(2) we have discussed the propriety of such relief in the present Memorandum pursuant to the directions of the Court. *See* Pretrial Order No. 72 (Doc. No. 1051) at ¶3.

[12] This question arises in two different procedural contexts. Where a party simply offers testimony by an expert that has not been timely disclosed, a court considers whether it should exclude the evidence as a "discovery sanction" under Fed.R.Civ.P. 37(b)(2)(B). *E.g., In re Paoli R.R. PCB Litig.* ("*Paoli II*"), 35 F.3d 717, 791 (3rd Cir. 1994). If a party

Corp., 696 F.3d 254, 297 (3rd Cir. 2012) ("the District Court has considerable discretion in matters regarding expert discovery and case management"). However, this discretion is "not unlimited." *ZF Meritor*, 696 F.3d at 298, *citing Konstantopoulos v. Westvaco Corp*., 112 F.3d 710, 719 (3rd Cir. 1997). Rather, the exercise of the District Court's discretion is governed by proper consideration of five factors:

> (1) "the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified" or the excluded evidence would have been offered; (2) "the ability of that party to cure the prejudice"; (3) the extent to which allowing such witnesses or evidence would "disrupt the orderly and efficient trial of the case or of other cases in the court"; (4) any "bad faith or willfulness in failing to comply with the court's order"; and (5) the importance of the excluded evidence.

ZF Meritor, 696 F.3d at 298 (citations omitted). *Accord, e.g., Paoli II*, 35 F.3d at 791; *DeMarines v. KLM Royal Dutch Airlines*, 580 F.2d 1193, 1201-02 (3rd Cir. 1978); *Meyers v. Pennypack Woods Home Ownership Assn*., 559 F.2d 894, 904-05 (3rd Cir. 1977).

In applying these factors, our Court of Appeals has repeatedly emphasized that "the exclusion of critical evidence is an 'extreme' sanction not normally to be imposed absent a showing of willful deception or 'flagrant disregard' of a court order by the proponent of the evidence." *Paoli II*, 35 F.3d at 791-92, *quoting Meyers*, 559 F.2d at 905 and *Dudley v. South Jersey Metal, Inc*., 555 F.2d 96, 99 (3rd Cir. 1977). And, it has explained "that a continuance, as opposed to exclusion, is the 'preferred means' of

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applies for an extension of the expert discovery deadline so that it may identify a new expert, the motion is decided with reference to Fed.R.Civ.P. 16(b)(4). *E.g., ZF Meritor*, 696 F.3d at 298. Regardless of the procedural context in which the question arises, however, the substantive considerations that govern resolution of the issue are exactly the same. *ZF Meritor*, 696 F.3d at 298, *citing Trilogy Communications, Inc. v. Times Fiber Communications, Inc.* 109 F.3d 739, 744-45 (Fed. Cir. 1997); *Hunt v. County of Orange*, 672 F.3d 606, 616 (9th Cir. 2012).

dealing with a party's attempt to offer new evidence after the time for discovery has closed." *ZF Meritor*, 696 F.3d at 297, *citing E.E.O.C. v. General Dynamics Corp.*, 999 F.2d 113, 116 (5th Cir. 1993). *Accord, e.g., Betzel v. State Farm Lloyds*, 480 F.3d 704, 708 (5th Cir. 2007); *Paoli II*, 35 F.3d at 792 ("the district court could easily have extended the [expert discovery] deadline" instead of precluding expert from testifying).

Given these principles, when critical testimony by a timely designated expert is excluded on *Daubert* grounds and the deadline for expert disclosures has passed, District Courts typically allow the proponent of the evidence to designate a new expert to testify on the same subject so long as there is no evidence of bad faith. *E.g*., *Boyd v. Southern Energy Homes, Inc*., No. 2:11-cv-118, 2012 WL 1601317 at 1-2 (S.D. Miss., May 7, 2012) (District Court exercises its discretion to allow plaintiffs to designate new expert after discovery cut-off date where original expert precluded from testifying under *Daubert*); *Krueger v. Johnson and Johnson Professional, Inc*., 160 F.Supp.2d 1026, 1032 (S.D. Iowa 2001) ("based on the Court's discretion in handling discovery matters, the Court finds it is warranted to reopen discovery for the limited purpose of allowing plaintiffs to designate a new expert witness" after the Court excluded plaintiffs' original expert from testifying); *In re Porter McLeod, Inc.*, 196 F.R.D. 389, 390-91 (D. Colo. 2000) (denial of a motion to designate a new expert in the place of an expert whose testimony was excluded "would lead to manifest injustice"). And when District Courts refuse to do so, Courts of Appeal, including the Third Circuit, have not hesitated to find such a refusal to be an abuse of discretion.[13] *E.g., ZF Meritor*, 696 F.3d at 297-300 (in an

[13] Pfizer's apparent reliance on the Third Circuit's *Three Mile Island* opinion to support the contrary proposition is clearly misplaced. In *Three Mile Island*, the Court of Appeals affirmed a District Court's refusal to permit what it found to be plaintiffs' bad faith

antitrust case where District Court excluded evidence of an antitrust damage calculation by Plaintiff's expert on *Daubert* grounds, the Court's refusal to then allow Plaintiff to furnish an amended report with a new damage calculation after the close of the period for expert discovery was an abuse of discretion given the critical nature of the excluded damage evidence and the fact that Defendants had an adequate opportunity to meet the untimely expert testimony on damages); *Summers v. Missouri Pac. RR Sys*., 132 F.3d 599, 604 (10th Cir.1997) (district court abused discretion in finding that plaintiff failed to show good cause to modify scheduling order to allow plaintiff to add expert after original expert disqualified); *Rimbert v. Eli Lilly & Co*., 647 F.3d 1247, 1256 (10th Cir. 2011) (trial court abused its discretion in disallowing request for additional time to name a substitute expert after *Daubert* ruling excluding expert). *See also Paoli II*, 35 F.3d at 792 (in case involving medical monitoring district court abused discretion in refusing to allow plaintiffs' expert to testify to elements of proposed monitoring plan that were first disclosed one month after the expert discovery date and four months prior to trial); *De Marines*, 580 F.2d at 1201-02 (district court abused discretion when it precluded proposed testimony by defense expert on the cause of plaintiff's injuries that was first disclosed during trial).

Application of these principles strongly weigh in favor of the Court exercising its discretion to amend its case management schedule to allow the PSC to identify Dr. Jewell

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request to permit new expert testimony where the litigation had been pending for 11 years, and where the Court had previously extended the exert discovery deadlines and adjourned the trial on "close to a dozen" occasions to allow plaintiffs multiple opportunities to present new expert testimony. *See In re TMI Litig*., 193 F.3d 613, 717-722. Clearly, none of those circumstances are present here.

as an expert who will offer testimony on general causation in accordance with the proffer reflected in the report attached as Exhibit "A" to this motion.

First, permitting the PSC to offer expert testimony by Dr. Jewell will not result in any prejudice to Pfizer let alone incurable prejudice. Contemporaneously with the filing of this motion, Pfizer is being furnished with a detailed report by Dr. Jewell that is predicated on a body of scientific data that is well known to Pfizer and its experts. Therefore, even if the first "bellwether" case in these MDL proceedings was still scheduled for trial on a date certain, Pfizer would have more than ample time to evaluate the report, depose Dr. Jewell and mount a *Daubert* challenge to his proposed testimony.[14]

Second, because no MDL case is presently scheduled to proceed to trial, allowing the PSC to offer testimony by Dr. Jewell on general causation will not disrupt the orderly and efficient trial of any of the Zoloft cases. Moreover, allowing the PSC the opportunity to present testimony by Dr. Jewell in lieu of the testimony of Dr. Bérard will eliminate the complexity, delay and expense that would inevitably flow from Pfizer's efforts to achieve summary judgment in individual cases based on the exclusion of Dr. Bérard's general causation testimony and to defend such judgments on appeal. *See* fns. 4-6 and accompanying text, *supra*. And that, in turn, would allow the MDL to go forward as a central force in the resolution of this mass tort litigation. *Id*. Thus, allowing the PSC to

[14] We recognize that Pfizer may claim that it is "prejudiced" because the delayed designation of Dr. Jewell will require it to incur increased defense costs. However, the cost of defending against a new expert has never been identified as a legally sufficient reason to exclude testimony by that expert. Moreover, it seems entirely likely that individual Zoloft plaintiffs will identify Dr. Jewell as an expert in their individual cases – either in federal court, in state court or both and that, therefore, Pfizer will be required to spend money to meet his testimony regardless of whether the present motion is granted or denied. Indeed, it would appear far more efficient and less expensive to vet his proposed testimony in a single *Daubert* proceeding before this Court than in a variety of case-specific proceedings.

present Dr. Jewell as a general causation expert in cases of cardiac defects would actually facilitate the orderly and efficient management of this litigation.

Third, there is no colorable basis to claim that the PSC has acted in bad faith with regard to the identification of expert testimony in the Zoloft MDL.

Fourth, and most critically, like the expert testimony on damages that the District Court declined to hear in *ZF Meritor*, Dr. Jewell's testimony is critically important to the plaintiffs in this litigation. Proof of general causation -- that exposure to Zoloft was capable of causing plaintiffs' injuries -- is a prerequisite to recovery by every plaintiff herein. Therefore, such testimony should be permitted even though it was, of necessity, first proffered after the original expert discovery cut-off date established by the Court.

Because all of the relevant factors weigh heavily in favor of allowing the PSC to present Dr. Jewell's expert testimony, we respectfully submit that the Court should enter an order amending the applicable case management deadlines to allow the PSC to designate Dr. Jewell as an expert on general causation to testify in accordance with the proffer reflected in the report appended as an exhibit to this motion.

B. Zoloft Plaintiffs Who Can Not Prove Causation Should be Permitted to Voluntarily Dismiss Their Civil Actions Without Prejudice

When the dust settles and the issues regarding the admissibility of causation testimony are fully and finally decided, there may be plaintiffs that are left without proof of causation based on the science as it currently exists. However, as we pointed out earlier, the Court has explicitly recognized that such proof may emerge from the ongoing scientific investigation of the teratogenicity of Zoloft during the lengthy limitations periods that apply to most of these minor plaintiffs. Despite this, Pfizer has insisted that the Court should summarily enter a judgment against these plaintiffs, foreclosing their

right to ever assert a birth defect claim against Pfizer irrespective of the strength of the emerging scientific evidence in support of such claims. This contention is at odds with the law.

With certain exceptions not applicable here, Fed.R.Civ.P. 41(a)(2) provides that "an action may be dismissed at the plaintiff's request only by court order, on terms that the court considers proper. *** Unless the order states otherwise, a dismissal under this paragraph (2) is without prejudice." Motions for voluntary dismissal without prejudice under Rule 41 should be granted, "unless defendant will suffer some prejudice other than the mere prospect of a second lawsuit." *In re: Paoli R.R. PCB Litig.* (*Paoli I*), 916 F.2d 829, 863 (3rd Cir. 1990). *Accord, e.g., In re Wellbutrin XL Antitrust Lit.*, 268 F.R.D. 539, 543 (E.D. Pa. 2010) ("Voluntary dismissal under Rule 41(a)(2) falls within the discretion of the district court. Dismissal, however, should be generally granted unless it would subject 'the defendant to plain prejudice beyond the prospect of subsequent litigation.'").

The factors to be considered in determining whether a defendant will suffer "plain prejudice" beyond the prospect of a second lawsuit are "(1) The excessive and duplicative expense of a second litigation; (2) The effort and expense incurred by the defendant in preparing for trial; (3) The extent to which the current suit has progressed; and (4) Plaintiff's diligence in bringing the motion to dismiss." *Maleski v. DP Realty Trust*, 162 F.R.D. 496. 498 (E.D.Pa. 1995), *citing Citizens Savings Ass'n. v. Franciscus*, 120 F.R.D. 22, 25 (M.D.Pa. 1988). *Accord*, *e.g.*, 9 Wright & Miller, FEDERAL PRACTICE AND PROCEDURE §2364 at 510-11 (3rd ed. 2008).

In applying these principles, the Courts have generally held that where a plaintiff's ability to prove a critical element of his or her cause of action depends on

events that may occur in the future, it is appropriate to dismiss the litigation without prejudice rather than enter summary judgment so that the plaintiff may pursue his or her claim when, and if future events make the claim a viable one. For example, in *Paoli I* certain "Butler plaintiffs" filed a complaint alleging that exposure to PCBs caused them both personal injury and property damage but later admitted that they did "not currently suffer from any adverse health effects as a result of their exposure to PCBs." *Paoli I*, 916 F.2d at 863. Then,

> Defendants moved for summary judgment based on the Butler plaintiffs' failure to produce evidence in support of their personal injury claims. In their response to this motion, the Butler plaintiffs sought leave to amend their complaint to eliminate the personal injury claims, pursuant to Fed.R.Civ.P. 41. The theory of this motion was that, although the Butlers were not then afflicted with injuries, the long latency periods often associated with toxic exposure could cause them to suffer injury in the future, thus making it advisable to preserve their personal injury claims until such time as any harm becomes manifest. Defendants, having already made significant investments in the instant litigation, opposed this motion, arguing that they would be prejudiced by the possibility of having to defend against these actions in the future. The [district] court, without explanation, summarily denied plaintiffs' motion for leave to amend, and granted summary judgment in favor of defendants.

Id. Noting the "liberal policy" governing disposition of Rule 41 motions and finding that defendants would not be "significantly prejudiced" by the amendment sought by plaintiffs, the Third Circuit held that the District Court abused its discretion in entering summary judgment against the Butler plaintiffs rather than allowing them to dismiss their personal injury claims without prejudice pursuant to Rule 41(a)(2). *Id.*

Even more to the point is the decision of Judge Weinstein in the *Agent Orange Litigation.* In that case the plaintiffs were children who sued the government claiming damages because they were born with birth defects as a result of their father's exposure to Agent Orange while engaged in military service in Vietnam. *In re Agent Orange*

Prods. Liab. Litig., 603 F. Supp.2d 239, 245-46 (E.D.N.Y. 1985), *aff'd in part and rev'd in part on other grounds*, 818 F.2d 194 (2nd Cir. 1987). The government moved for summary judgment on these claims on the grounds that there was "as yet no epidemiological evidence that paternal veteran exposure to Agent Orange caused birth defects…." *Id*. at 247. While the District Court agreed that scientific proof of causation did not then exist, it declined to enter summary judgment and instead dismissed the minor plaintiffs' claims without prejudice because of the prospect that such scientific evidence might develop in the future:

> In most of the cases against the government plaintiffs' counsel moved for voluntary dismissal under Rule 41(a)(2) of the minor childrens' independent claims. The court agrees that it would be both reasonable and fair to avoid dismissing the childrens' claims on the merits when the scientific evidence may not as yet have been fully developed. The government, consistent with its harsh and unyielding view of its relationship to the veterans, their wives and children in this litigation strongly urges that the infants' cases be dismissed on the merits and with prejudice so that they can never sue again, even if evidence subsequently shows that they have a valid claim against the government.
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> Rule 41(a)(2) of the Federal Rules of Civil Procedure grants the court broad discretion to permit a voluntary withdrawal without prejudice at this stage of the litigation. **Absent a showing of substantial harm to the defendant, discretion should generally be exercised in favor of an infant who lacks evidence to support his or her claim but who may obtain such evidence in the future. Added reason to favor the infants exists when, as here, following the governments' view would bar a handful of children who have already sued while leaving the thousands of potential claimants who have not sued free to do so in the future**. ***
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> The prospect of defending a future lawsuit by these plaintiffs does not constitute "plain legal prejudice" to the government.
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> It would be unfair to dismiss on the merits the claims of infant children whose counsel did not move for voluntary dismissal. All infants' claims are, therefore, dismissed without prejudice.

Id. at 247-48 (citations omitted; emphasis supplied).

Like the plaintiffs in *Paoli I* and *Agent Orange*, certain minor plaintiffs in the Zoloft MDL litigation may currently lack evidence to support one key element of their respective claims but may very well acquire such evidence in the future. Like the plaintiffs in those cases they should not be foreclosed from asserting claims that may become viable and available to hundreds of similarly situated persons simply because they prematurely filed a federal lawsuit. Thus, absent a demonstration of "significant prejudice" to Pfizer, instead of ultimately entering summary judgment against them the Court should simply allow their cases to be discontinued without prejudice. In light of the factors that inform a Court's determination of the presence of "significant prejudice" in the Rule 41 context, it is difficult to see how Pfizer will sustain its burden to show that it will be "significantly prejudiced" unless these claims are subject to the preclusive effects of a final, adverse judgment on the merits.

First, because these papers were filed about a month after the entry of the last of the two orders signaling an issue with proof of causation, it cannot be fairly contended that plaintiffs were anything but diligent in pursuing a without prejudice dismissal of their claims under Rule 41.

Second, the prospect of Rule 41 without prejudice dismissals was raised by the PSC at a relatively early stage in these MDL proceedings. Case-specific discovery has only occurred in the twenty-five Initial Discovery Pool cases, no case-specific experts have been identified and no cases have been listed for trial.

Third, in the event that science emerges that more fully buttresses proof of causation for a given class of birth defects, hundreds of individuals with those defects will be free to sue Pfizer and, as Judge Weinstein remarked in his *Agent Orange* opinion,

it hardly seems fair to bar any tort recovery by the relative handful of children who have already sued while leaving the hundreds of potential claimants who have not yet sued free to do so in the future.

Fourth, Rule 41 allows a District Court to impose conditions on a voluntary dismissal for the purpose of protecting a defendant from prejudice while, at the same time, preserving a plaintiff's legitimate rights to recovery. *E.g., Wellbutrin*, 568 F.R.D. at 543, *citing* 9 WRIGHT & MILLER, FEDERAL PRACTICE AND PROCEDURE, § 2366 (3rd ed. 2008) ("Terms and conditions are generally imposed by the district court under Rule 41(a)(2) for the protection of the defendant from such prejudice"). Therefore, to the extent that the Court is concerned Pfizer "will suffer some prejudice other than the mere prospect of a second lawsuit" as a result of a without prejudice dismissal the Court can remedy that prejudice by imposing conditions upon the dismissal. For example, to the extent that the Court perceives a genuine risk that plaintiffs are forum shopping in an effort to escape its *Daubert* rulings, rather than seeking dismissal to preserve their rights to demonstrate causation based on future advances in the science, the Court could condition leave to voluntarily dismiss on the requirement that plaintiffs refile their claims in federal court for a reasonable period of time following the dismissal, thus assuring that this Court's *Daubert* rulings would continue to apply absent a change in the science. *E.g., American Nat'l. Bank and Trust Col of Sapula v. Bic Corp.*, 931 F.2d 1411, 1412 (10th Cir. 1991) (District Court had the power to impose federal refiling required incident to Rule 41 dismissal without prejudice even though it properly exercised its discretion in deciding not to impose such a condition); *Williams v. Laboratory Corp. of Am.*, No. 301

CV 0514, 2001 WL 896922 at *3 (N.D. Tex. Aug. 3, 2010 (federal refiling requirement incident to without prejudice dismissal).

For all of these reasons, minor plaintiffs who are left without legally cognizable testimony on causation should be given leave to dismiss their claims without prejudice subject to whatever conditions the Court deems appropriate, if any.

III. CONCLUSION

For all of the foregoing reasons, the PSC respectfully submits that the Court should enter an order granting the PSC's Motion for Leave to Identify and Present a New General Causation Expert.

Dated: September 30, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of September, 2014, I electronically filed the foregoing PSC's Motion for Leave to Identify and Present a New General Causation Expert with the Clerk of Court using the CM/ECF system, which shall send electronic notification of such filing to all CM/ECF participants.

/s/ Joseph J. Zonies